

# PATENT COOPERATION TREATY

**P&V**

23 NOV. 1995

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From the  
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

**PCT**

WRITTEN OPINION

(PCT Rule 66)

To:

**PLOUGMANN & VINGTOFT A/S**  
Sankt Annae Plads 11  
DK - 1021 Copenhagen K  
DANEMARK

Date of mailing  
(day/month/year)

23.11.95

Applicant's or agent's file reference

4150 PC 1

REPLY DUE

within 3 months/days  
from the above date of mailing

International application No.

PCT/DK 95/00080

International filing date (day/month/year)

23/02/1995

Priority date (day/month/year)

23/02/1994

International Patent Classification (IPC) or both national classification and IPC

A61K9/22

Applicant

BUKH MEDITEC

1. This written opinion is the First (first, etc.) drawn up by this International Preliminary Examining Authority.

2. This report contains indications and corresponding pages relating to the following items:

- I ☒ Basis of the opinion
- II ☐ Priority
- III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

3. The applicant is hereby invited to reply to this opinion.

**When?** See the time limit indicated above. The applicant may, before the expiration of that time limit, request this Authority to grant an extension, see Rule 66.2(d).

**How?** By submitting a written reply, accompanied, where appropriate, by amendments, according to Rule 66.3. For the form and the language of the amendments, see Rules 66.8 and 66.9.

**Also** For an additional opportunity to submit amendments, see Rule 66.4.  
For the examiner's obligation to consider amendments and/or arguments, see Rule 66.4bis.  
For an informal communication with the examiner, see Rule 66.6.

If no reply is filed, the international preliminary examination report will be established on the basis of this opinion.

4. The final date by which the international preliminary examination report must be established according to Rule 69.2 is: 23/06/1996

Name and mailing address of the IEPA/



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Authorized officer

Examiner

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Pamela Tatum

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I. Basis of the opinion

1. This opinion has been drawn up on the basis of (Substitute sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this opinion as "originally filed".):

☒ the international application as originally filed.

☐ the description, pages \_\_\_\_\_, as originally filed,  
pages \_\_\_\_\_, filed with the demand,  
pages \_\_\_\_\_, filed with the letter of \_\_\_\_\_,

☐ the claims, Nos. \_\_\_\_\_, as originally filed,  
Nos. \_\_\_\_\_, as amended under Article 19,  
Nos. \_\_\_\_\_, filed with the demand,  
Nos. \_\_\_\_\_, filed with the letter of \_\_\_\_\_,

☐ the drawings, sheets/fig \_\_\_\_\_, as originally filed,  
sheets/fig \_\_\_\_\_, filed with the demand,  
sheets/fig \_\_\_\_\_, filed with the letter of \_\_\_\_\_,

2. The amendments have resulted in the cancellation of:

☐ the description, pages \_\_\_\_\_.  
☐ the claims, Nos. \_\_\_\_\_.  
☐ the drawings, sheets/fig \_\_\_\_\_.

3. ☐ This opinion has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

4. Additional observations, if necessary:

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V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step and industrial applicability; citations and explanations supporting such statement

1. STATEMENT

Novelty (N)	Claims 1-27 Yes _____
	Claims _____
Inventive Step (IS)	Claims 1-27 NO _____
	Claims _____
Industrial Applicability (IA)	Claims 1-17 YES _____
	Claims _____

2. CITATIONS AND EXPLANATIONS

1. The following documents are mentioned for the first time in this written opinion; the numbering will be adhered to in the rest of the procedure:

D1 = WO89/09066

D2 = WO91/0401

D3 = DE-A-2 415 490

2. Having regard to the documents cited in the international search report, the subject-matter of claims 1-27, is considered as being novel according to Article 33 (2) PCT, as a composition for controlled delivery comprising a matrix and a coating, as defined in said claims 1-27, has not been described in any of the cited documents.
3. However, the present application does not satisfy the criterion set forth in Article 33(3) PCT because the subject-matter of Claims 1-27 does not involve an inventive step (Rule 65(1)(2) PCT).

The problem to be solved by the present invention may be regarded as formulating a composition for controlled delivery of an active substance into an aqueous medium. The proposed solution is given by the composition, subject-matter of claim 1, which does not involve an inventive step for the following reasons, after considering that:

- i) said composition comprises a matrix and a coating;
  - ii) the matrix is known from documents D1 and D2; and
  - iii) the coating comprising a cellulose derivative which is insoluble in the aqueous medium in which the composition is to be used, and at least one of a plasticizer, a filler and/or a cellulose derivative which is insoluble in water.
- iii) is the only new element in order to obtain the controlled delivery and the combination of two cellulose derivatives with different properties or one cellulose derivative with fillers is known in the art (see for example claims 1-9 and pages 1-7 of document D3). Therefore, the skilled person would regard it as a normal design option to include this combination in the coating of the matrix described in documents D1 and D2 in order to solve the problem posed.

Only if the claimed coating combination of the present application produce surprising results (other than what could be expected) vs. any of the combinations a) to m) (page 6-7) of document D3 regarding controlled delivery of an active from identical matrix according to the present invention; the inventive step of the composition of claim 1 would be reconsidered.

4. Dependent Claims 2-27 do not appear to contain any additional features which, in combination with the features of any claim to which they refer, involve an inventive step.

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5. The claimed invention (claims 1-27) is considered industrially applicable (Article 33 (4) PCT) as the claimed gel composition should be manufactured in the industry.